PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
PU03100-PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2004/002007	2004-12-21	2003-12-23
International Patent Classification (IPC) or national classification and IPC		
See Supplemental Box		
Applicant		
Amersham Biosciences AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15-06-2005	13-03-2006
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Form PCT/IPEA/409 (cover sheet) (April 2005)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Cover sheet

International patent classification (IPC)

B01D 15/00 (2006.01)
B01J 20/22 (2006.01)
B01J 20/32 (2006.01)
C07K 1/20 (2006.01)
C07K 16/06 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/002007

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____ ,
which is the language of a translation furnished for the purposes of:

☐ international search (Rules 12.3(a) and 23.1(b))

☐ publication of the international application (Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/002007

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-28	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-28	NO
Industrial applicability (IA)	Claims	1-28	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present application pertains to a separation matrix for isolation of antibodies. The matrix is composed of a porous support to which ligands comprising at least one aliphatic sulphonamide have been immobilised. The application also describes a chromatography column which contains the described matrix.

The problem to be solved by the present application is to separate antibodies at a low ionic strength and at pH values around neutral. The solution to this problem is to provide a separation matrix according to the claimed invention wherein ligands comprising one or more sulphonamides have been immobilised to a porous support. It is characterized by the R-group of the sulphonyl being an aliphatic compound. A method using the claimed matrix does not require any addition of detergent to achieve adsorption and it enables highly selective adsorption of antibodies.

The following documents, cited in the international search report, are considered to be of particular relevance:

D1: US 4725355
D2: EP 0197521

D1 discloses a body fluid purification medium comprising a support and an adsorbent for separation of pathogenic substances such as immunoglobulins and immune complexes (see column 3, lines 12-26). The matrix comprises a sulphonamide characterised by an R group being hydrogen, methylcarbonyl, guanidine, pyridine, 1,3-diazine, merazine, methazine, isomidine, azole or a derivative thereof (see column 4, lines

.../...

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Box V

1-13). The R group is preferably an aromatic group. The support is capable of selectively adsorbing pathogenic substances in blood.

D2 discloses an immunoglobulin adsorbent which comprises a hydroxyl-containing water-insoluble carrier to which a diamine compound has been attached. The compound has been attached through a silane coupling agent and the R group constitutes of an aromatic group.

D1 is considered to represent the closest prior art.

The claimed matrix differs from the known matrix of D1 in that the R group of the sulphonyl is an aliphatic compound instead of hydrogen, methylcarbonyl, guanidine, pyridine, 1,3-diazine, merazine, methazine, isomidine, azole or a derivative thereof.

The problem to be solved by this difference is to obtain a separation process for immunoglobulins which can be performed at low ionic strength and at pH values around neutral.

However, since it is previously known from D1 a matrix comprising a sulphonyl group wherein the R group can be i.a. hydrogen it is considered to be an obvious alternative for a person skilled in the art to exchange the R group to an aliphatic compound.

Also, the separation matrix can only be considered as patentable if it presents an unexpected effect compared to the known matrixes in the above cited documents. This unexpected effect must also be valid for the whole scope of the claims (see Box VIII).

Claims 1-28 are novel but are not considered to involve an inventive step. The claims are industrially applicable.

Also in view of D2 the claimed invention is considered to lack inventive step. It is considered an obvious alternative for a person skilled in the art to exchange the R group from an aromatic group, known from D2, to an aliphatic compound.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims do not disclose the invention in a sufficiently clear manner. The breath of the claims should be such that it represents a reasonable generalisation of the examples provided, and such that it is credible that every compound falling within the scope actually provides a solution to the problem underlying the invention. See Article 6. The examples in the description relate to sulphonamides wherein the ligand is choosen from cysteamine, triethylenetetramine, diethylenetriamine,pentaethylenehexamine and polyethyleneimine whereas the claims relate to the broad definition "sulphonamides wherein the R group of the sulphonyl is an aliphatic compound".